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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,004	01/24/2002	Kenneth J Breslauer	RU-0124	6792

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EXAMINER
TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,004	Applicant(s) Breslauer et al.
	Examiner Joyce Tung	Art Unit 1637

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 12, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above, claim(s) *33-37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-17, 19, 22, 25-32, and 38-45* is/are rejected.

7) ☒ Claim(s) *18, 20, 21, 23, and 24* is/are objected to.

8) ☒ Claims *1-37* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. The amendment filed 2/12/2003 has been entered. Following the entry of the amendment, claims 1-45 are pending and claims 33-37 are non-elected group.

2. Regarding the restriction requirement, the response argues that the references U.S. Patent 5,972,612 was not raised rejection in the Office action.

Claims lack a special technic feature because the reference, U.S. Patent 5,972,612, anticipates claim 1 as set forth in the Office action mailed 8/13/2002. A lack of unity requirement is proper.

3. The objection of the specification is withdrawn.

4. The objection of claims 16-29 is withdrawn.

5. The rejection of claims 1-15 and 30-32 under 35 U.S.C. §112, second paragraph is withdrawn.

6. Claims 1-15 and 30-32 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Albrecht et al. (6,265,163) in view of Drmanac et al. (5,525,464) and Breslauer et al. (Proc. Natl. Acad. Sci USA, 1988, Vol. 83, pg. 3748-3750).

The response argues that the disruption step is not taught by either Albrecht et al. or Drmanac et al.. The response further argues that how the thermodynamic data 10 nearest neighbor interactions possible in a Watson-Crick DNA duplex structure from the teachings of Breslauer et al. can be used to predict the stability and the melting behavior of any DNA duplex from its primary sequence.

Response to Amendment

However, as indicated by Breslauer et al. the motivation is that this capability would prove valuable in predicting the stability of gene-probe complex selecting optimal conditions for hybridization, deciding on the minimum length of a probe, predicting the influence of specific transversion or transition on the stability of an affected DNA region (See pg. 3746, the Abstract).

In addition, regarding the phrase "the disruption step", since in the claim there is no further limit to the phrase "the disruption step" that there is physical disruption or chemical disruption of the initial nucleic acid duplex, based upon understanding the claim language the phrase "the disruption step" is interpreted as in regular nucleic acid hybridization, that is the nucleic acid duplex which is heated for denaturing to be a single stranded nucleic acid. Then the single stranded nucleic acid is hybridized to a target DNA strand recited in claim 1, step (c).

Albrecht et al. disclose the use of a method for competitive hybridization (See column 17 lines 13-49). One of ordinary skill in the art would have understood that there is heat denaturing to get a single stranded nucleic acid and the single stranded nucleic acid hybridizes to its complementary strand.

Drmanac et al. disclose the theoretical principal of oligonucleotide hybridization to filter bound target nucleic acids (See column 14, line 22 to column 17, line 58).

Thus, based upon the analysis above one of ordinary skill in the art would have combined the teachings of Albrecht et al., Drmanac et al. and Breslauer et al. to screen nucleic acid duplex stability by competitive equilibria. Therefore, the rejection is maintained.

Response to Amendment

7. Claims 16-17, 19, 22, 25-28, and 39-45 are also rejected under 35 U.S.C. §103(a) as being unpatentable over Albrecht et al. (6,265,163) in view of Drmanac et al. (5,525,464) and Breslauer et al. (Proc. Natl. Acad. Sci USA, 1988, Vol. 83, pg. 3748-3750).

Albrecht et al. disclose a method for identifying and isolating differentially expressed genes or polymorphic genes on the basis of labels that generate different optical signals (See column 2, lines 28-33). The DNA population is differently labeled by fluorescence (See column 2, lines 43-57). The differently labeled DNA population are competitively hybridized with reference DNA cloned on solid supports (See column 2, lines 43-57).

Albrecht et al. do not disclose using competitive hybridization to screen the stability of nucleic acid duplex.

Drmanac et al. disclose the theoretical principal of oligonucleotide hybridization to filter bound target nucleic acids (See column 14, line 22 to column 17, line 58).

Breslauer et al. disclose that this capability would prove valuable in predicting the stability of gene-probe complex selection optimal conditions for hybridization, deciding on the minimum length of a probe, predicting the influence of specific transversion or transition on the stability of an affected DNA region (See pg. 3746, the Abstract).

Thus, based upon the analysis above one of ordinary skill in the art would have combined the teachings of Albrecht et al., Drmanac et al. and Breslauer et al. to screen nucleic acid duplex stability by competitive equilibria. It would have been prima facie obvious to carry out the method of screening nucleic acid duplex stability by competitive equilibria.

Response to Amendment

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht et al. (6,265,163) in view of Drmanac et al. (5,525,464) and Breslauer et al. (Proc. Natl. Acad. Sci USA, 1988, Vol. 83, pg. 3748-3750) as applied to claims 1-17, 19, 22, 25-28, 30-32 and 39-45 above, and further in view of Malmqvist (5,972,612).

Albrecht et al., Drmanac et al. and Breslauer et al. do not disclose using surface plasmon resonance spectroscopy to monitor the changes in initial nucleic acid duplex.

Malmqvist discloses a method of analyzing nucleic acid sequences comprising measuring by surface detection technique (See the Abstract). The optical method is surface plasmon resonance spectroscopy (See column 6, lines 44-57).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply surface plasmon resonance spectroscopy (See column 6, lines 44-57) to the method of Albrecht et al. because by using plasmon resonance spectroscopy, the measurement of the binding interaction between the first and second nucleic acid corresponding to full complementary is performed at permitting equilibrium rapidly attained. It has been prima facie obvious to screen the nucleic acid duplex stability by using plasmon resonance spectroscopy.

Claim Rejections - 35 USC § 112

8. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response to Amendment

a. Claim 38 is vague and indefinite because claim 4 depends from claim 1 which is a method of screening for nucleic acid duplex stability by competitive equilibria, while claim 38 recites a method for extraction enthalpy data. It is unclear whether the method of claim 1 further includes the step for extracting enthalpy data. Clarification is required.

Allowable Subject Matter

9. Claims 18, 20-21 and 23-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

Concerns claims 18, 20-21 and 23-24, there is no prior art that teaches or suggests a method of screening the nucleic acid duplex stability by measuring changes in FET donor or acceptor intensity.

11. No claims are allowable.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Response to Amendment

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

April 10, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600